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AN ACT

RELATING TO HEALTH COVERAGE; ENACTING NEW SECTIONS OF THE HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE ORGANIZATION LAW AND THE NONPROFIT HEALTH CARE PLAN LAW TO ESTABLISH GUIDELINES RELATING TO STEP THERAPY FOR PRESCRIPTION DRUG COVERAGE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the Health Care Purchasing Act is enacted to read:

"PRESCRIPTION DRUG COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

A. Group health coverage, including any form of self-insurance, offered, issued or renewed under the Health Care Purchasing Act that provides coverage for prescription drugs for which any step therapy protocols are required shall establish clinical review criteria for those step therapy protocols. The clinical review criteria shall be based on clinical practice guidelines that:

(1) recommend that the prescription drugs subject to step therapy protocols be taken in the specific sequence required by the step therapy protocol;

(2) are developed and endorsed by an interdisciplinary panel of experts that manages conflicts of

1 interest among the members of the panel of experts by:

2 (a) requiring members to: 1) disclose
3 any potential conflicts of interest with group health plan
4 administrators, insurers, health maintenance organizations,
5 health care plans, pharmaceutical manufacturers, pharmacy
6 benefits managers and any other entities; and 2) recuse
7 themselves if there is a conflict of interest; and

8 (b) using analytical and methodological
9 experts to work to provide objectivity in data analysis and
10 ranking of evidence through the preparation of evidence
11 tables and facilitating consensus;

12 (3) are based on high-quality studies,
13 research and medical practice;

14 (4) are created pursuant to an explicit and
15 transparent process that:

16 (a) minimizes bias and conflicts of
17 interest;

18 (b) explains the relationship between
19 treatment options and outcomes;

20 (c) rates the quality of the evidence
21 supporting recommendations; and

22 (d) considers relevant patient
23 subgroups and preferences; and

24 (5) take into account the needs of atypical
25 patient populations and diagnoses.

1 B. In the absence of clinical guidelines that meet
2 the requirements of Subsection A of this section,
3 peer-reviewed publications may be substituted.

4 C. When a group health plan restricts coverage of
5 a prescription drug for the treatment of any medical
6 condition through the use of a step therapy protocol, an
7 enrollee and the practitioner prescribing the prescription
8 drug shall have access to a clear, readily accessible and
9 convenient process to request a step therapy exception
10 determination. A group health plan may use its existing
11 medical exceptions process in accordance with the provisions
12 of Subsections D through I of this section to satisfy this
13 requirement. The process shall be made easily accessible for
14 enrollees and practitioners on the group health plan's
15 publicly accessible website.

16 D. A group health plan shall expeditiously grant
17 an exception to the group health plan's step therapy
18 protocol, based on medical necessity and a clinically valid
19 explanation from the patient's prescribing practitioner as to
20 why a drug on the plan's formulary that is therapeutically
21 equivalent to the prescribed drug should not be substituted
22 for the prescribed drug, if:

23 (1) the prescription drug that is the
24 subject of the exception request is contraindicated or will
25 likely cause an adverse reaction by or physical or mental

1 harm to the patient;

2 (2) the prescription drug that is the
3 subject of the exception request is expected to be
4 ineffective based on the known clinical characteristics of
5 the patient and the known characteristics of the prescription
6 drug regimen;

7 (3) while under the enrollee's current
8 health coverage or previous health coverage, the enrollee has
9 tried the prescription drug that is the subject of the
10 exception request or another prescription drug in the same
11 pharmacologic class or with the same mechanism of action as
12 the prescription drug that is the subject of the exception
13 request and that prescription drug was discontinued due to
14 lack of efficacy or effectiveness, diminished effect or an
15 adverse event; or

16 (4) the prescription drug required pursuant
17 to the step therapy protocol is not in the best interest of
18 the patient, based on clinical appropriateness, because the
19 patient's use of the prescription drug is expected to:

20 (a) cause a significant barrier to the
21 patient's adherence to or compliance with the patient's plan
22 of care;

23 (b) worsen a comorbid condition of the
24 patient; or

25 (c) decrease the patient's ability to

1 achieve or maintain reasonable functional ability in
2 performing daily activities.

3 E. Upon the granting of an exception to a group
4 health plan's step therapy protocol, the group health plan
5 administrator shall authorize coverage for the prescription
6 drug that is the subject of the exception request.

7 F. A group health plan shall respond with its
8 decision on an enrollee's exception request within
9 seventy-two hours of receipt. In cases where exigent
10 circumstances exist, a group health plan shall respond within
11 twenty-four hours of receipt of the exception request. In
12 the event the group health plan does not respond to an
13 exception request within the time frames required pursuant to
14 this subsection, the exception request shall be granted.

15 G. A group health plan administrator's denial of a
16 request for an exception for step therapy protocols shall be
17 subject to review and appeal pursuant to the Patient
18 Protection Act.

19 H. After an enrollee has made an exception request
20 in accordance with the provisions of this section, a group
21 health plan shall authorize continued coverage of a
22 prescription drug that is the subject of the exception
23 request pending the determination of the exception request.

24 I. The provisions of this section shall not be
25 construed to prevent a:

1 (1) group health plan from requiring a
2 patient to try a generic equivalent of a prescription drug
3 before providing coverage for the equivalent brand-name
4 prescription drug; or

5 (2) practitioner from prescribing a
6 prescription drug that the practitioner has determined to be
7 medically necessary.

8 J. The provisions of this section shall apply only
9 to a group health plan delivered, issued for delivery or
10 renewed on or after January 1, 2019.

11 K. As used in this section, "medical necessity" or
12 "medically necessary" means health care services determined
13 by a practitioner, in consultation with the group health plan
14 administrator, to be appropriate or necessary according to:

15 (1) any applicable, generally accepted
16 principles and practices of good medical care;

17 (2) practice guidelines developed by the
18 federal government or national or professional medical
19 societies, boards or associations; or

20 (3) any applicable clinical protocols or
21 practice guidelines developed by the group health plan
22 consistent with federal, national and professional practice
23 guidelines. These standards shall be applied to decisions
24 related to the diagnosis or direct care and treatment of a
25 physical or behavioral health condition, illness, injury or

1 disease."

2 SECTION 2. A new section of the Public Assistance Act
3 is enacted to read:

4 "MEDICAL ASSISTANCE--PRESCRIPTION DRUG COVERAGE--STEP
5 THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

6 A. By January 1, 2019, the secretary shall require
7 any medical assistance plan for which any step therapy
8 protocols are required to establish clinical review criteria
9 for those step therapy protocols. The clinical review
10 criteria shall be based on clinical practice guidelines that:

11 (1) recommend that the prescription drugs
12 subject to step therapy protocols be taken in the specific
13 sequence required by the step therapy protocol;

14 (2) are developed and endorsed by an
15 interdisciplinary panel of experts that manages conflicts of
16 interest among the members of the panel of experts by:

17 (a) requiring members to: 1) disclose
18 any potential conflicts of interest with health care plans,
19 medical assistance plans, health maintenance organizations,
20 pharmaceutical manufacturers, pharmacy benefits managers and
21 any other entities; and 2) recuse themselves if there is a
22 conflict of interest; and

23 (b) using analytical and methodological
24 experts to work to provide objectivity in data analysis and
25 ranking of evidence through the preparation of evidence

1 tables and facilitating consensus;

2 (3) are based on high-quality studies,
3 research and medical practice;

4 (4) are created pursuant to an explicit and
5 transparent process that:

6 (a) minimizes bias and conflicts of
7 interest;

8 (b) explains the relationship between
9 treatment options and outcomes;

10 (c) rates the quality of the evidence
11 supporting recommendations; and

12 (d) considers relevant patient
13 subgroups and preferences; and

14 (5) take into account the needs of atypical
15 patient populations and diagnoses.

16 B. In the absence of clinical guidelines that
17 meet the requirements of Subsection A of this section,
18 peer-reviewed publications may be substituted.

19 C. When a medical assistance plan restricts
20 coverage of a prescription drug for the treatment of any
21 medical condition through the use of a step therapy protocol,
22 a recipient and the practitioner prescribing the prescription
23 drug shall have access to a clear, readily accessible and
24 convenient process to request a step therapy exception
25 determination. A medical assistance plan may use its

1 existing medical exceptions process in accordance with the
2 provisions of Subsections D through I of this section to
3 satisfy this requirement. The process shall be made easily
4 accessible for recipients and practitioners on the medical
5 assistance plan's publicly accessible website.

6 D. A medical assistance plan shall expeditiously
7 grant an exception to the medical assistance plan's step
8 therapy protocol, based on medical necessity and a clinically
9 valid explanation from the patient's prescribing practitioner
10 as to why a drug on the plan's formulary that is
11 therapeutically equivalent to the prescribed drug should not
12 be substituted for the prescribed drug, if:

13 (1) the prescription drug that is the
14 subject of the exception request is contraindicated or will
15 likely cause an adverse reaction by or physical or mental
16 harm to the patient;

17 (2) the prescription drug that is the
18 subject of the exception request is expected to be
19 ineffective based on the known clinical characteristics of
20 the patient and the known characteristics of the prescription
21 drug regimen;

22 (3) while under the recipient's current
23 medical assistance plan, or under the recipient's previous
24 health coverage, the recipient has tried the prescription
25 drug that is the subject of the exception request or another

1 prescription drug in the same pharmacologic class or with the
2 same mechanism of action as the prescription drug that is the
3 subject of the exception request and that prescription drug
4 was discontinued due to lack of efficacy or effectiveness,
5 diminished effect or an adverse event; or

6 (4) the prescription drug required pursuant
7 to the step therapy protocol is not in the best interest of
8 the patient, based on clinical appropriateness, because the
9 patient's use of the prescription drug is expected to:

10 (a) cause a significant barrier to the
11 patient's adherence to or compliance with the patient's plan
12 of care;

13 (b) worsen a comorbid condition of the
14 patient; or

15 (c) decrease the patient's ability to
16 achieve or maintain reasonable functional ability in
17 performing daily activities.

18 E. Upon the granting of an exception to a medical
19 assistance plan's step therapy protocol, a medical assistance
20 plan shall authorize coverage for the prescription drug that
21 is the subject of the exception request.

22 F. A medical assistance plan shall respond with
23 its decision on a recipient's exception request within
24 seventy-two hours of receipt. In cases where exigent
25 circumstances exist, a medical assistance plan shall respond

1 within twenty-four hours of receipt of the exception request.
2 In the event the medical assistance plan does not respond to
3 an exception request within the time frames required pursuant
4 to this subsection, the exception request shall be granted.

5 G. A medical assistance plan's denial of a request
6 for an exception for step therapy protocols shall be subject
7 to review and appeal pursuant to department rules.

8 H. After a recipient has made an exception request
9 in accordance with the provisions of this section, a medical
10 assistance plan shall authorize continued coverage of a
11 prescription drug that is the subject of the exception
12 request pending the determination of the exception request.

13 I. The provisions of this section shall not be
14 construed to prevent:

15 (1) a medical assistance plan from requiring
16 a patient to try a generic equivalent of a prescription drug
17 before providing coverage for the equivalent brand-name
18 prescription drug; or

19 (2) a practitioner from prescribing a
20 prescription drug that the practitioner has determined to be
21 medically necessary.

22 J. As used in this section, "medical necessity" or
23 "medically necessary" means health care services determined
24 by a practitioner, in consultation with the medical
25 assistance plan, to be appropriate or necessary, according

1 to:

2 (1) any applicable, generally accepted
3 principles and practices of good medical care;

4 (2) practice guidelines developed by the
5 federal government or national or professional medical
6 societies, boards or associations; or

7 (3) any applicable clinical protocols or
8 practice guidelines developed by the medical assistance plan
9 consistent with federal, national and professional practice
10 guidelines. These standards shall be applied to decisions
11 related to the diagnosis or direct care and treatment of a
12 physical or behavioral health condition, illness, injury or
13 disease."

14 SECTION 3. A new section of Chapter 59A, Article 22
15 NMSA 1978 is enacted to read:

16 "PRESCRIPTION DRUG COVERAGE--STEP THERAPY PROTOCOLS--
17 CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

18 A. Each individual health insurance policy, health
19 care plan and certificate of health insurance delivered or
20 issued for delivery in this state that provides a
21 prescription drug benefit for which any step therapy
22 protocols are required shall establish clinical review
23 criteria for those step therapy protocols. The clinical
24 review criteria shall be based on clinical practice
25 guidelines that:

1 (1) recommend that the prescription drugs
2 subject to step therapy protocols be taken in the specific
3 sequence required by the step therapy protocol;

4 (2) are developed and endorsed by an
5 interdisciplinary panel of experts that manages conflicts of
6 interest among the members of the panel of experts by:

7 (a) requiring members to: 1) disclose
8 any potential conflicts of interest with insurers, health
9 maintenance organizations, health care plans, pharmacy
10 benefits managers and any other entities; and 2) recuse
11 themselves if there is a conflict of interest; and

12 (b) using analytical and methodological
13 experts to work to provide objectivity in data analysis and
14 ranking of evidence through the preparation of evidence
15 tables and facilitating consensus;

16 (3) are based on high-quality studies,
17 research and medical practice;

18 (4) are created pursuant to an explicit and
19 transparent process that:

20 (a) minimizes bias and conflicts of
21 interest;

22 (b) explains the relationship between
23 treatment options and outcomes;

24 (c) rates the quality of the evidence
25 supporting recommendations; and

1 (d) considers relevant patient
2 subgroups and preferences; and

3 (5) take into account the needs of atypical
4 patient populations and diagnoses.

5 B. In the absence of clinical guidelines that
6 meet the requirements of Subsection A of this section,
7 peer-reviewed publications may be substituted.

8 C. When a health insurance policy, health care
9 plan or certificate of insurance restricts coverage of a
10 prescription drug for the treatment of any medical condition
11 through the use of a step therapy protocol, an insured and
12 the practitioner prescribing the prescription drug shall have
13 access to a clear, readily accessible and convenient process
14 to request a step therapy exception determination. An
15 insurer may use its existing medical exceptions process in
16 accordance with the provisions of Subsections D through I of
17 this section to satisfy this requirement. The process shall
18 be made easily accessible for insureds and practitioners on
19 the insurer's publicly accessible website.

20 D. An insurer shall expeditiously grant an
21 exception to the health insurance policy's, health care
22 plan's or certificate of insurance's step therapy protocol,
23 based on medical necessity and a clinically valid explanation
24 from the patient's prescribing practitioner as to why a drug
25 on the health insurance policy's, health care plan's or

1 certificate of insurance's formulary that is therapeutically
2 equivalent to the prescribed drug should not be substituted
3 for the prescribed drug, if:

4 (1) the prescription drug that is the
5 subject of the exception request is contraindicated or will
6 likely cause an adverse reaction by or physical or mental
7 harm to the patient;

8 (2) the prescription drug that is the
9 subject of the exception request is expected to be
10 ineffective based on the known clinical characteristics of
11 the patient and the known characteristics of the prescription
12 drug regimen;

13 (3) while under the insured's current health
14 insurance policy, health care plan or certificate of
15 insurance, or under the insured's previous health coverage,
16 the insured has tried the prescription drug that is the
17 subject of the exception request or another prescription drug
18 in the same pharmacologic class or with the same mechanism of
19 action as the prescription drug that is the subject of the
20 exception request and that prescription drug was discontinued
21 due to lack of efficacy or effectiveness, diminished effect
22 or an adverse event; or

23 (4) the prescription drug required pursuant
24 to the step therapy protocol is not in the best interest of
25 the patient, based on clinical appropriateness, because the

1 patient's use of the prescription drug is expected to:

2 (a) cause a significant barrier to the
3 patient's adherence to or compliance with the patient's plan
4 of care;

5 (b) worsen a comorbid condition of the
6 patient; or

7 (c) decrease the patient's ability to
8 achieve or maintain reasonable functional ability in
9 performing daily activities.

10 E. Upon the granting of an exception to a health
11 insurance policy's, health care plan's or certificate of
12 insurance's step therapy protocol, an insurer shall authorize
13 coverage for the prescription drug that is the subject of the
14 exception request.

15 F. An insurer shall respond with its decision on
16 an insured's exception request within seventy-two hours of
17 receipt. In cases where exigent circumstances exist, an
18 insurer shall respond within twenty-four hours of receipt of
19 the exception request. In the event the insurer does not
20 respond to an exception request within the time frames
21 required pursuant to this subsection, the exception request
22 shall be granted.

23 G. An insurer's denial of a request for an
24 exception for step therapy protocols shall be subject to
25 review and appeal pursuant to the Patient Protection Act.

1 H. After an insured has made an exception request
2 in accordance with the provisions of this section, an insurer
3 shall authorize continued coverage of a prescription drug
4 that is the subject of the exception request pending the
5 determination of the exception request.

6 I. The provisions of this section shall not be
7 construed to prevent:

8 (1) a health insurance policy, health care
9 plan or certificate of insurance from requiring a patient to
10 try a generic equivalent of a prescription drug before
11 providing coverage for the equivalent brand-name prescription
12 drug; or

13 (2) a practitioner from prescribing a
14 prescription drug that the practitioner has determined to be
15 medically necessary.

16 J. The provisions of this section shall apply only
17 to a health insurance policy, health care plan or certificate
18 of insurance delivered, issued for delivery or renewed on or
19 after January 1, 2019.

20 K. The superintendent shall promulgate rules as
21 may be necessary to appropriately implement the provisions of
22 this section.

23 L. Nothing in this section shall be interpreted to
24 interfere with the superintendent's authority to regulate
25 prescription drug coverage benefits under other state and

1 federal law.

2 M. As used in this section, "medical necessity" or
3 "medically necessary" means health care services determined
4 by a practitioner, in consultation with the insurer, to be
5 appropriate or necessary, according to:

6 (1) any applicable, generally accepted
7 principles and practices of good medical care;

8 (2) practice guidelines developed by the
9 federal government or national or professional medical
10 societies, boards or associations; or

11 (3) any applicable clinical protocols or
12 practice guidelines developed by the insurer consistent with
13 federal, national and professional practice guidelines.

14 These standards shall be applied to decisions related to the
15 diagnosis or direct care and treatment of a physical or
16 behavioral health condition, illness, injury or disease."

17 SECTION 4. A new section of Chapter 59A, Article 23
18 NMSA 1978 is enacted to read:

19 "PRESCRIPTION DRUG COVERAGE--STEP THERAPY PROTOCOLS--
20 CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

21 A. Each group or blanket health insurance policy,
22 health care plan and certificate of health insurance
23 delivered or issued for delivery in this state that provides
24 a prescription drug benefit for which any step therapy
25 protocols are required shall establish clinical review

1 criteria for those step therapy protocols. The clinical
2 review criteria shall be based on clinical practice
3 guidelines that:

4 (1) recommend that the prescription drugs
5 subject to step therapy protocols be taken in the specific
6 sequence required by the step therapy protocol;

7 (2) are developed and endorsed by an
8 interdisciplinary panel of experts that manages conflicts of
9 interest among the members of the panel of experts by:

10 (a) requiring members to: 1) disclose
11 any potential conflicts of interest with insurers, health
12 maintenance organizations, health care plans, pharmacy
13 benefits managers and any other entities; and 2) recuse
14 themselves if there is a conflict of interest; and

15 (b) using analytical and methodological
16 experts to provide objectivity in data analysis and ranking
17 of evidence through the preparation of evidence tables and
18 facilitating consensus;

19 (3) are based on high-quality studies,
20 research and medical practice;

21 (4) are created pursuant to an explicit and
22 transparent process that:

23 (a) minimizes bias and conflicts of
24 interest;

25 (b) explains the relationship between

1 treatment options and outcomes;

2 (c) rates the quality of the evidence
3 supporting recommendations; and

4 (d) considers relevant patient
5 subgroups and preferences; and

6 (5) take into account the needs of atypical
7 patient populations and diagnoses.

8 B. In the absence of clinical guidelines that
9 meet the requirements of Subsection A of this section,
10 peer-reviewed publications may be substituted.

11 C. When a health insurance policy, health care
12 plan or certificate of insurance restricts coverage of a
13 prescription drug for the treatment of any medical condition
14 through the use of a step therapy protocol, an insured and
15 the practitioner prescribing the prescription drug shall have
16 access to a clear, readily accessible and convenient process
17 to request a step therapy exception determination. An
18 insurer may use its existing medical exceptions process in
19 accordance with the provisions of Subsections D through I of
20 this section to satisfy this requirement. The process shall
21 be made easily accessible for insureds and practitioners on
22 the insurer's publicly accessible website.

23 D. An insurer shall expeditiously grant an
24 exception to the health insurance policy's, health care
25 plan's or certificate of insurance's step therapy protocol,

1 based on medical necessity and a clinically valid explanation
2 from the patient's prescribing practitioner as to why a drug
3 on the health insurance policy's, health care plan's or
4 certificate of insurance's formulary that is therapeutically
5 equivalent to the prescribed drug should not be substituted
6 for the prescribed drug, if:

7 (1) the prescription drug that is the
8 subject of the exception request is contraindicated or will
9 likely cause an adverse reaction by or physical or mental
10 harm to the patient;

11 (2) the prescription drug that is the
12 subject of the exception request is expected to be
13 ineffective based on the known clinical characteristics of
14 the patient and the known characteristics of the prescription
15 drug regimen;

16 (3) while under the insured's current health
17 insurance policy, health care plan or certificate of
18 insurance, or under the insured's previous health coverage,
19 the insured has tried the prescription drug that is the
20 subject of the exception request or another prescription drug
21 in the same pharmacologic class or with the same mechanism of
22 action as the prescription drug that is the subject of the
23 exception request and that prescription drug was discontinued
24 due to lack of efficacy or effectiveness, diminished effect
25 or an adverse event; or

1 (4) the prescription drug required pursuant
2 to the step therapy protocol is not in the best interest of
3 the patient, based on clinical appropriateness, because the
4 patient's use of the prescription drug is expected to:

5 (a) cause a significant barrier to the
6 patient's adherence to or compliance with the patient's plan
7 of care;

8 (b) worsen a comorbid condition of the
9 patient; or

10 (c) decrease the patient's ability to
11 achieve or maintain reasonable functional ability in
12 performing daily activities.

13 E. Upon the granting of an exception to a health
14 insurance policy's, health care plan's or certificate of
15 insurance's step therapy protocol, an insurer shall authorize
16 coverage for the prescription drug that is the subject of the
17 exception request.

18 F. An insurer shall respond with its decision on
19 an insured's exception request within seventy-two hours of
20 receipt. In cases where exigent circumstances exist, an
21 insurer shall respond within twenty-four hours of receipt of
22 the exception request. In the event the insurer does not
23 respond to an exception request within the time frames
24 required pursuant to this subsection, the exception request
25 shall be granted.

1 G. An insurer's denial of a request for an
2 exception for step therapy protocols shall be subject to
3 review and appeal pursuant to the Patient Protection Act.

4 H. After an insured has made an exception request
5 in accordance with the provisions of this section, an insurer
6 shall authorize continued coverage of a prescription drug
7 that is the subject of the exception request pending the
8 determination of the exception request.

9 I. The provisions of this section shall not be
10 construed to prevent:

11 (1) a health insurance policy, health care
12 plan or certificate of insurance from requiring a patient to
13 try a generic equivalent of a prescription drug before
14 providing coverage for the equivalent brand-name prescription
15 drug; or

16 (2) a practitioner from prescribing a
17 prescription drug that the practitioner has determined to be
18 medically necessary.

19 J. The provisions of this section shall apply only
20 to a health insurance policy, health care plan or certificate
21 of insurance delivered, issued for delivery or renewed on or
22 after January 1, 2019.

23 K. The superintendent shall promulgate rules as
24 may be necessary to appropriately implement the provisions of
25 this section.

1 L. Nothing in this section shall be interpreted to
2 interfere with the superintendent's authority to regulate
3 prescription drug coverage benefits under other state and
4 federal law.

5 M. As used in this section, "medical necessity" or
6 "medically necessary" means health care services determined
7 by a practitioner, in consultation with the insurer, to be
8 appropriate or necessary, according to:

9 (1) any applicable, generally accepted
10 principles and practices of good medical care;

11 (2) practice guidelines developed by the
12 federal government or national or professional medical
13 societies, boards or associations; or

14 (3) any applicable clinical protocols or
15 practice guidelines developed by the insurer consistent with
16 federal, national and professional practice guidelines.

17 These standards shall be applied to decisions related to the
18 diagnosis or direct care and treatment of a physical or
19 behavioral health condition, illness, injury or disease."

20 SECTION 5. A new section of the Health Maintenance
21 Organization Law is enacted to read:

22 "PRESCRIPTION DRUG COVERAGE--STEP THERAPY PROTOCOLS--
23 CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

24 A. Each individual or group health maintenance
25 organization contract delivered or issued for delivery in

1 this state that provides a prescription drug benefit for
2 which any step therapy protocols are required shall establish
3 clinical review criteria for those step therapy protocols.

4 The clinical review criteria shall be based on clinical
5 practice guidelines that:

6 (1) recommend that the prescription drugs
7 subject to step therapy protocols be taken in the specific
8 sequence required by the step therapy protocol;

9 (2) are developed and endorsed by an
10 interdisciplinary panel of experts that manages conflicts of
11 interest among the members of the panel of experts by:

12 (a) requiring members to: 1) disclose
13 any potential conflicts of interest with carriers, insurers,
14 health care plans, pharmaceutical manufacturers, pharmacy
15 benefits managers and any other entities; and 2) recuse
16 themselves if there is a conflict of interest; and

17 (b) using analytical and methodological
18 experts to work to provide objectivity in data analysis and
19 ranking of evidence through the preparation of evidence
20 tables and facilitating consensus;

21 (3) are based on high-quality studies,
22 research and medical practice;

23 (4) are created pursuant to an explicit and
24 transparent process that:

25 (a) minimizes bias and conflicts of

1 interest;

2 (b) explains the relationship between
3 treatment options and outcomes;

4 (c) rates the quality of the evidence
5 supporting recommendations; and

6 (d) considers relevant patient
7 subgroups and preferences; and

8 (5) take into account the needs of atypical
9 patient populations and diagnoses.

10 B. In the absence of clinical guidelines that
11 meet the requirements of Subsection A of this section,
12 peer-reviewed publications may be substituted.

13 C. When a health maintenance organization contract
14 restricts coverage of a prescription drug for the treatment
15 of any medical condition through the use of a step therapy
16 protocol, an enrollee and the practitioner prescribing the
17 prescription drug shall have access to a clear, readily
18 accessible and convenient process to request a step therapy
19 exception determination. A carrier may use its existing
20 medical exceptions process in accordance with the provisions
21 of Subsections D through I of this section to satisfy this
22 requirement. The process shall be made easily accessible for
23 enrollees and practitioners on the carrier's publicly
24 accessible website.

25 D. A carrier shall expeditiously grant an

1 exception to the health maintenance organization contract's
2 step therapy protocol, based on medical necessity and a
3 clinically valid explanation from the patient's prescribing
4 practitioner as to why a drug on the health maintenance
5 organization contract's formulary that is therapeutically
6 equivalent to the prescribed drug should not be substituted
7 for the prescribed drug, if:

8 (1) the prescription drug that is the
9 subject of the exception request is contraindicated or will
10 likely cause an adverse reaction by or physical or mental
11 harm to the patient;

12 (2) the prescription drug that is the
13 subject of the exception request is expected to be
14 ineffective based on the known clinical characteristics of
15 the patient and the known characteristics of the prescription
16 drug regimen;

17 (3) while under the enrollee's current
18 health maintenance organization contract, or under the
19 enrollee's previous health coverage, the enrollee has tried
20 the prescription drug that is the subject of the exception
21 request or another prescription drug in the same
22 pharmacologic class or with the same mechanism of action as
23 the prescription drug that is the subject of the exception
24 request and that prescription drug was discontinued due to
25 lack of efficacy or effectiveness, diminished effect or an

1 adverse event; or

2 (4) the prescription drug required pursuant
3 to the step therapy protocol is not in the best interest of
4 the patient, based on clinical appropriateness, because the
5 patient's use of the prescription drug is expected to:

6 (a) cause a significant barrier to the
7 patient's adherence to or compliance with the patient's plan
8 of care;

9 (b) worsen a comorbid condition of the
10 patient; or

11 (c) decrease the patient's ability to
12 achieve or maintain reasonable functional ability in
13 performing daily activities.

14 E. Upon the granting of an exception to a health
15 maintenance organization contract's step therapy protocol, a
16 carrier shall authorize coverage for the prescription drug
17 that is the subject of the exception request.

18 F. A carrier shall respond with its decision on an
19 enrollee's exception request within seventy-two hours of
20 receipt. In cases where exigent circumstances exist, a
21 carrier shall respond within twenty-four hours of receipt of
22 the exception request. In the event the carrier does not
23 respond to an exception request within the time frames
24 required pursuant to this subsection, the exception request
25 shall be granted.

1 G. A carrier's denial of a request for an
2 exception for step therapy protocols shall be subject to
3 review and appeal pursuant to the Patient Protection Act.

4 H. After an enrollee has made an exception request
5 in accordance with the provisions of this section, a carrier
6 shall authorize continued coverage of a prescription drug
7 that is the subject of the exception request pending the
8 determination of the exception request.

9 I. The provisions of this section shall not be
10 construed to prevent:

11 (1) a health maintenance organization
12 contract from requiring a patient to try a generic equivalent
13 of a prescription drug before providing coverage for the
14 equivalent brand-name prescription drug; or

15 (2) a practitioner from prescribing a
16 prescription drug that the practitioner has determined to be
17 medically necessary.

18 J. The provisions of this section shall apply only
19 to a health maintenance organization contract delivered,
20 issued for delivery or renewed on or after January 1, 2019.

21 K. The superintendent shall promulgate rules as
22 may be necessary to appropriately implement the provisions of
23 this section.

24 L. Nothing in this section shall be interpreted to
25 interfere with the superintendent's authority to regulate

1 prescription drug coverage benefits under other state and
2 federal law.

3 M. As used in this section, "medical necessity" or
4 "medically necessary" means health care services determined
5 by a practitioner, in consultation with the carrier, to be
6 appropriate or necessary, according to:

7 (1) any applicable, generally accepted
8 principles and practices of good medical care;

9 (2) practice guidelines developed by the
10 federal government or national or professional medical
11 societies, boards or associations; or

12 (3) any applicable clinical protocols or
13 practice guidelines developed by the carrier consistent with
14 federal, national and professional practice guidelines.

15 These standards shall be applied to decisions related to the
16 diagnosis or direct care and treatment of a physical or
17 behavioral health condition, illness, injury or disease."

18 SECTION 6. A new section of the Nonprofit Health Care
19 Plan Law is enacted to read:

20 "PRESCRIPTION DRUG COVERAGE--STEP THERAPY PROTOCOLS--
21 CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

22 A. Each individual or group nonprofit health care
23 plan contract delivered or issued for delivery in this state
24 that provides a prescription drug benefit for which any step
25 therapy protocols are required shall establish clinical

1 review criteria for those step therapy protocols. The
2 clinical review criteria shall be based on clinical practice
3 guidelines that:

4 (1) recommend that the prescription drugs
5 subject to step therapy protocols be taken in the specific
6 sequence required by the step therapy protocol;

7 (2) are developed and endorsed by an
8 interdisciplinary panel of experts that manages conflicts of
9 interest among the members of the panel of experts by:

10 (a) requiring members to: 1) disclose
11 any potential conflicts of interest with health care plans,
12 insurers, health maintenance organizations, pharmaceutical
13 manufacturers, pharmacy benefits managers and any other
14 entities; and 2) recuse themselves if there is a conflict of
15 interest; and

16 (b) using analytical and methodological
17 experts to work to provide objectivity in data analysis and
18 ranking of evidence through the preparation of evidence
19 tables and facilitating consensus;

20 (3) are based on high-quality studies,
21 research and medical practice;

22 (4) are created pursuant to an explicit and
23 transparent process that:

24 (a) minimizes bias and conflicts of
25 interest;

1 (b) explains the relationship between
2 treatment options and outcomes;

3 (c) rates the quality of the evidence
4 supporting recommendations; and

5 (d) considers relevant patient
6 subgroups and preferences; and

7 (5) take into account the needs of atypical
8 patient populations and diagnoses.

9 B. In the absence of clinical guidelines that meet
10 the requirements of Subsection A of this section,
11 peer-reviewed publications may be substituted.

12 C. When a health care plan restricts coverage of a
13 prescription drug for the treatment of any medical condition
14 through the use of a step therapy protocol, a subscriber and
15 the practitioner prescribing the prescription drug shall have
16 access to a clear, readily accessible and convenient process
17 to request a step therapy exception determination. A health
18 care plan may use its existing medical exceptions process in
19 accordance with the provisions of Subsections D through I of
20 this section to satisfy this requirement. The process shall
21 be made easily accessible for subscribers and practitioners
22 on the health care plan's publicly accessible website.

23 D. A health care plan shall expeditiously grant an
24 exception to the health care plan's step therapy protocol,
25 based on medical necessity and a clinically valid explanation

1 from the patient's prescribing practitioner as to why a drug
2 on the health care plan's formulary that is therapeutically
3 equivalent to the prescribed drug should not be substituted
4 for the prescribed drug, if:

5 (1) the prescription drug that is the
6 subject of the exception request is contraindicated or will
7 likely cause an adverse reaction by or physical or mental
8 harm to the patient;

9 (2) the prescription drug that is the
10 subject of the exception request is expected to be
11 ineffective based on the known clinical characteristics of
12 the patient and the known characteristics of the prescription
13 drug regimen;

14 (3) while under the subscriber's current
15 health care plan, or under the subscriber's previous health
16 coverage, the subscriber has tried the prescription drug that
17 is the subject of the exception request or another
18 prescription drug in the same pharmacologic class or with the
19 same mechanism of action as the prescription drug that is the
20 subject of the exception request and that prescription drug
21 was discontinued due to lack of efficacy or effectiveness,
22 diminished effect or an adverse event; or

23 (4) the prescription drug required pursuant
24 to the step therapy protocol is not in the best interest of
25 the patient, based on clinical appropriateness, because the

1 patient's use of the prescription drug is expected to:

2 (a) cause a significant barrier to the
3 patient's adherence to or compliance with the patient's plan
4 of care;

5 (b) worsen a comorbid condition of the
6 patient; or

7 (c) decrease the patient's ability to
8 achieve or maintain reasonable functional ability in
9 performing daily activities.

10 E. Upon the granting of an exception to a health
11 care plan's step therapy protocol, a health care plan shall
12 authorize coverage for the prescription drug that is the
13 subject of the exception request.

14 F. A health care plan shall respond with its
15 decision on a subscriber's exception request within
16 seventy-two hours of receipt. In cases where exigent
17 circumstances exist, a health care plan shall respond within
18 twenty-four hours of receipt of the exception request. In
19 the event the insurer does not respond to an exception
20 request within the time frames required pursuant to this
21 subsection, the exception request shall be granted.

22 G. A health care plan's denial of a request for an
23 exception for step therapy protocols shall be subject to
24 review and appeal pursuant to the Patient Protection Act.

25 H. After a subscriber has made an exception

1 request in accordance with the provisions of this section, a
2 health care plan shall authorize continued coverage of a
3 prescription drug that is the subject of the exception
4 request pending the determination of the exception request.

5 I. The provisions of this section shall not be
6 construed to prevent:

7 (1) a health care plan from requiring a
8 patient to try a generic equivalent of a prescription drug
9 before providing coverage for the equivalent brand-name
10 prescription drug; or

11 (2) a practitioner from prescribing a
12 prescription drug that the practitioner has determined to be
13 medically necessary.

14 J. The provisions of this section shall apply only
15 to a health care plan delivered, issued for delivery or
16 renewed on or after January 1, 2019.

17 K. The superintendent shall promulgate rules as
18 may be necessary to appropriately implement the provisions of
19 this section.

20 L. Nothing in this section shall be interpreted to
21 interfere with the superintendent's authority to regulate
22 prescription drug coverage benefits under other state and
23 federal law.

24 M. As used in this section, "medical necessity" or
25 "medically necessary" means health care services determined

1 by a practitioner, in consultation with the health care plan,
2 to be appropriate or necessary, according to:

3 (1) any applicable, generally accepted
4 principles and practices of good medical care;

5 (2) practice guidelines developed by the
6 federal government or national or professional medical
7 societies, boards or associations; or

8 (3) any applicable clinical protocols or
9 practice guidelines developed by the health care plan
10 consistent with federal, national and professional practice
11 guidelines. These standards shall be applied to decisions
12 related to the diagnosis or direct care and treatment of a
13 physical or behavioral health condition, illness, injury or
14 disease." _____

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